DETAILED ACTION

1. This action is in response to the amendment filed December 20, 2007. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection.

Claim 20 is pending and has been examined herein.

This action is made final.

Claim Rejections - 35 USC § 112 – New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not appear to provide support for the amendment to claim 20 to recite a method comprising the step of comparing the expression of "a mouse ortholog of SFRP1 (SEQ ID NO: 15) mRNA" in kidney samples of a mouse before and after administration of an agent to determine if said agent modulates expression of the mouse ortholog of an SFRP1.

In the reply of December 20, 2007, Applicants point to paragraphs [0025], [0034] and Table 4 as providing support for this amendment. A review of the cited passages

indicates that paragraph [0025] provides support only for the concept of methods for identifying agents that modulate the expression of an “LRG” gene wherein the agent is administered to a subject, such as an animal model. Paragraph [0034] describes Table 1 which lists “human orthologs” of mouse LRG genes, including the LRG gene of SFRP1. Table 4 (page 72) lists the mouse gene "sfrp1," the "Homo sapiens ortholog" of SFRP1, and the change in expression of lupus affected tissues relative to disease-free tissues. Accordingly, the cited passages discuss only a human ortholog of the mouse SFRP1 gene. Further, the specification (pages 66 and 69) teaches that the mouse SFRP1 mRNA was detected using the Affymetrix Mu11KsubA and Mu11KsubB oligonucleotide arrays comprising probes that specifically hybridize to the mouse SFRP1 mRNA. The specification does not, however, provide support for a method of administering an agent to a mouse with lupus, and comparing expression of any mouse ortholog of any SFRP1 mRNA or an SFRP1 mRNA that is SEQ ID NO: 15 in a kidney sample before and after said administering to determine if said agent modulates expression of the mouse ortholog of any SFRP1 in the mouse. Thereby, it does not appear that the specification as originally filed provides basis for claim 20 as amended.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/
Primary Examiner, Art Unit 1634